K063388

510(k) SUMMARY

JUN 22 2007

Topcon Corporation's
3D OCT-1000 Optical Coherence Tomography System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Topcon Corporation
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174

Additional Correspondents:

Topcon Medical System, Inc.
37 West Century Road
Paramus, NJ 07652
Phone: (201) 599-5153
Facsimile: (201) 599-5240
Contact Person: Beth Zelnick Kaufman

OR

Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004
Phone: (202) 637-5794
Facsimile: (202) 637-5910

Date Prepared: November 8, 2006

Name of Device and Name/Address of Sponsor

Topcon 3D OCT-1000 Optical System Tomography System

Topcon Corporation
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174

Common or Usual Name

AC- Powered Ophthalmoscope

Classification Name

Ophthalmoscope; 21 C.F.R. 886.1570

Predicate Devices

Carl Zeiss, Inc., Humphrey OCT Scanner
Carl Zeiss Ophthalmic Systems, Inc.'s, Humphrey OCT 3

Intended Use / Indications for Use

The Topcon 3D OCT-1000 is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging of the retina, retinal nerve fiber layer and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema and central serous retinopathy.

Technological Characteristics

Both the Topcon 3D OCT-1000 and the predicate devices have similar technological characteristics. The Topcon 3D OCT-1000 and the predicate devices use optical coherence tomography, which relies upon interferometry of superluminescent diode light reflected from the fundus of the eye to obtain cross-sectional images of the retina.

In addition, both the Topcon 3D OCT-1000 and the predicate devices have similar components. The components of the Topcon 3D OCT-1000 include a Main Unit, which houses three optical systems for observing and photographing the retina, a Power Supply Unit, a chin rest, a Spectroscope, and the ability to connect a personal computer for image viewing and analysis. Similarly, the Carl Zeiss, Inc. Humphrey OCT Scanner the Carl Zeiss Ophthalmic Systems, Inc.'s, Humphrey OCT 3 utilize optical systems for observing and photographing the retina, a digital signal processing (DSP) unit for obtaining interferometric signal and converting to retinal tomograms, a chin rest, and connection to a computer for viewing and analyzing captured images.

The Topcon 3D OCT-1000 also uses similar light sources as the Carl Zeiss, Inc. Humphrey OCT Scanner and the Carl Zeiss Ophthalmic Systems, Inc.'s, Humphrey OCT 3, and thus has optical equivalency.

Performance Data

The maximum exposure has been demonstrated to be well below the accepted threshold limits set out in IEC 60825-1:2001. In all instances, the Topcon 3D OCT-1000 functioned as intended.

In total, Topcon collected 55 images from 31 eyes, including at least seven pairs each from subjects with normal eyes, macular holes, cystoid macular edema (CME) and epiretinal membrane (ERM), as well as both dry and wet form age-related macular degeneration. All images were obtained using both the 3D OCT-1000 device and a predicate device. Paired images were independently graded by two graders using predefined diagnostic image criteria. In all of the 55 pairs of images, the graders (with the consensus score) demonstrated that the Topcon image met as many or more image criteria to support a diagnostic use of the image than the predicate device image. Specifically, the Topcon image was scored as meeting the same number of image quality criteria to support its diagnostic use in 81 of the 110 scorings, and as meeting more of the predefined criteria in 29 of the 110 scorings. Thus, the Topcon image met the same or more criteria than the predicate device image for an overall agreement of 100% (110 of 110 images).

Substantial Equivalence

The Topcon 3D OCT-1000 is as safe and effective as the Carl Zeiss, Inc., Humphrey OCT Scanner and the Carl Zeiss Ophthalmic Systems, Inc.'s, Humphrey OCT 3. The Topcon 3D OCT-1000 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the 3D OCT-1000 and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Topcon 3D OCT is as safe and effective as the Carl Zeiss Humphrey OCT device. Thus, the 3D OCT-1000 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Topcon Corporation
c/o Hogan & Hartson LLP
555 Thirteenth St NW
Columbia Square
Washington, DC 20004
Attn: Jonathan Kahan

JUN 22 2007

Re: K063388
Trade/Device Name: 3D OCT-1000 Optical Coherence Tomography System
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope, AC-Powered
Regulatory Class: Class II
Product Code: OBO
Dated: May 23, 2007
Received: May 23, 2007

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063388

Device Name: Topcon 3D OCT-1000

Indications for Use:

The Topcon 3D OCT-1000 is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging of the retina, retinal nerve fiber layer and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema and central serous retinopathy.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
on of Ophthalmic Ear,
nd Throat Devises

K) Number K063388

Page ____ of ____